

New York State Horticultural Society

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Food and Drug Administration
Dockets Management Branch (HFA-305)
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Comments on the Proposed FDA Guidance Document on Good Agricultural Practices for Fresh Fruits and Vegetables.

1. Guidance Development Process

The current timeline is too short to allow adequate industry input into the guidance development process. Commodity organizations such as ours are very short on resources, and are often unable to fully analyze such lengthy proposals in so short a period of time. Additional opportunities for industry input must be offered. The FDA must understand the need to completely study the diversity of agriculture in the Northeast, and note the contrasts with other agricultural regions of the country. The USDA should be designated the lead agency for interacting with producers and packer/shippers. USDA personnel already have an understanding of production agriculture, whereas FDA personnel would need to devote many hours of training, and still would lack the "institutional experience" and historical perspective of the USDA.

2. Existing Regulations already on the books need to be considered

New York State regulatory agencies such as the Department of Agriculture & Markets, The Department of Environmental Conservation, and the Department of Health all currently have regulatory authority concerning, many, if not most, of the issues addressed in the draft Guidance Document. State agencies need to be the front line of our mutual efforts to protect the health and well-being of our citizens. State agencies are closer to local practices which the federal government may not fully understand. State agencies already have effective working relationships with industry on a number of issues, such as microbial contamination of cider. Federal OSHA has regulations in place governing field sanitation on farms. Although the regulations are directed at protecting workers, it would be a better solution to modify existing regulations to include consumer protection, rather than introduce another set of regulations (and regulators) for industry to follow.

3. Federal Guidance is very likely to be become industry standards, enforced by produce buyers.

Understanding that the Draft Proposal is "Guidance" only, the reality is that guidance today will become regulation tomorrow. This could happen without further government involvement though the actions and policies of produce buyers who mandate adherence to the guidance by their suppliers in an effort to protect themselves from civil liability. We are arguing that the fact that the Draft Proposal is merely "Guidance" is not a rationale to relax the rigor of the science behind the recommendations.

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4. Guidance must be based drawn from research based on sound science.

At this time, not enough is known about the life cycles of various human pathogens when subjected to existing fresh produce production and packing/shipping practices. For example, steps to isolate wildlife from surface water used for irrigation may sound fine in theory, but may not be possible in practice, or even scientifically necessary. Industry resources wasted in attempting to control the inconsequential results in lost profitability, and lost opportunity to address what scientific study indicates are the more serious issues. The proposed Draft Guidance contains many grammatical modifiers such as "will likely", "may need", and "should be" used to minimize the actual facts that we do not have a scientific basis on which to base effective recommendations. Specific recommendations must only be made when the scientific justification exists. If good science is not available, that appropriate research must be funded. Once research identified specific practices which will improve the microbial safety of fresh produce, then adequate funds must be provided to the Cooperative Extension Service to disseminate this information to the industry.

5. Commodity Specific guidance is not necessary

General guidance will be adequate in the foreseeable future. The research base is deficient when it comes to the detail required of effective commodity specific recommendations. We are strongly opposed to the identification of specific produce commodities as "targets" for commodity specific guidance. Such targeting will only serve to cast a shadow on the safety of the targeted commodity in the eyes of the public. Selecting commodity targets based on sales volume would certainly be unfair, unscientific, and would do nothing to protect the public. Conversely, the science does not exist to adequately select targets based on risk. Regional differences in climate, soils, cultural practices, and packing/shipping technology further complicate the accuracy of commodity specific guidance.

6. Prevalence of small fruit farms, farm markets, PYO operations in the Northeast make for a food distribution system which contrasts greatly with large wholesale oriented operations.

Guidance developed on the basis of common industry practices relative to large commercial wholesalers and retailers may not be compatible with the special needs of the small farmer-operated produce stand, or the on-farm Pick-Your-Own operation. Such businesses are very popular in the Northeastern United States, and are becoming increasingly so. Small farm businesses may not have access to the financial capital and expertise needed to implement complicated procedures and technologies more appropriate to the requirements of large retail operations.

7. Specific Comment on Apples.

Manure is not commonly used in the annual production of an apple crop. Manure may be pre-plant incorporated prior to the planting of the tree, but a minimum of three years will pass before the first crop of apples is harvested. Some apple orchards are irrigated in New York State. Of those that are, the vast majority are drip (trickle) irrigated. Irrigation water sources are of all types, including municipal, private well, rivers, lakes, ponds, and swamps. Except for the rare use of a municipal water supply, irrigation water sources are not commonly tested for pathogens. Such tests are expensive, approximately \$25 per test per pathogen. Drip irrigation is much more efficient with water, and is possible because overhead water is not used as a frost control strategy.

Water for crop protection sprays is also drawn from a wide range of sources, implementing the

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appropriate level of backflow protection. This water is commonly not tested. Apples almost always sorted using a water flume as a transportation medium, and then sorted on various types of mechanical equipment. Flume water is usually changed weekly, but fresh water rapidly becomes contaminated with field dirt and debris even under the best of circumstances. Flume water is not usually filtered. Chlorine treatment is technically possible, but problematic in practice. Apples are stored and transported in 20 bushel hardwood pallet boxes. Apple boxes have a life expectancy of approximately 10 years. Field conditions on fruit farms do allow for the practical and economic "cleaning" of apple boxes. New technology plastic boxes are becoming more available, but are currently priced some 50% higher than a comparable wood box. Bulk apples are transported in the 20 bushel boxes on various sizes of flatbed trucks and tractor trailers. During the 10 week Fall harvest season, these trucks are used exclusively for apples or other plant-based products, and do not backhaul animals or related contaminants. Packed freshmarket apples are transported in cardboard bushel boxes, palletized, and loaded onto refrigerated trucks of various sizes. Some trucks are owned by the actual packer/shipper, others are assigned to the job by a broker. Suitability of the truck is the responsibility of the produce packer/shipper.

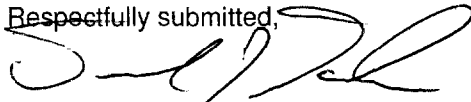
8. Specific Comments on Plum/Prune, Peach, and Sweet Cherries.

Please refer to comment on apples. Major differences are that packing and sorting practice do not involve the use of water. An exception is the practice of hydrocooling sweet cherries, but this is very rare in New York. Stonefruit are not stored bulk for any substantial length of time.

9. Specific Comments on Strawberries

Manure is used in the culture of strawberries, it may or may not be composted. Strawberries are not grown under plastic in New York. Drip irrigation is rare, and generally not economical. Overhead irrigation is a requirement both to supply moisture to the plants and provide a degree of frost protection to the blossoms in the spring. All harvest work is by hand. Picked strawberries are sorted dry, and handled both in the field and in the shipping process in very small units, less than 10lbs each. Water sources are similar to apples.

Respectfully submitted,



Daniel J. Donahue
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New York State Horticultural Society

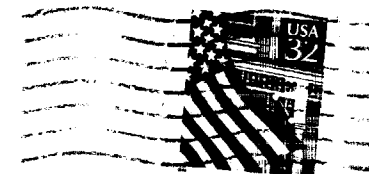


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